IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
5:15-CV-319-D

CUMBERLAND COUNTY HOSPITAL SYSTEM, INC. d/b/a CAPE FEAR VALLEY HEALTH SYSTEM, Plaintiff, v. THOMAS E. PRICE,[1] Secretary of the United States Department of Health and Human Services, Defendant.	)	**MEMORANDUM AND RECOMMENDATION**

In this action, plaintiff Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System ("plaintiff" or "CFVHS") challenges the final decision of defendant Secretary of the United States Department of Health and Human Services ("HHS") Thomas E. Price ("the Secretary") concerning plaintiff's claims for Medicare reimbursement for services it provided to patients identified herein as M.H. and C.B.[2] (or in context individually, "the patient" or "the beneficiary"). The case is before the court on the parties' motions for judgment on the pleadings. D.E. 67, 69. The motions were referred to the undersigned magistrate judge for a memorandum and recommendation pursuant to 28 U.S.C. § 636(b)(1)(B). *See* D.E. 75. For the reasons set forth below, it will be recommended that plaintiff's motion be allowed, the Secretary's motion be

[1] Thomas E. Price has succeeded the former defendant, Sylvia Matthews Burwell, as Secretary of the United States Department of Health and Human Services, and has been substituted for her as the defendant in this case pursuant to Fed. R. Civ. P. 25(d) ("An action does not abate when a public officer who is a party in an official capacity . . . ceases to hold office while the action is pending. The officer's successor is automatically substituted as a party.").

[2] To protect the patients' privacy, they are referred to solely by their initials throughout this Memorandum and Recommendation.

denied, the Secretary's final decision denying plaintiff's claims be reversed, and this case be remanded for reimbursement of plaintiff by the Secretary.

BACKGROUND

I. STANDARDS FOR MEDICARE APPEALS PROCESS

"Medicare is a federal program providing subsidized health insurance for the aged and disabled [and] [t]he Secretary of Health and Human Services . . . is charged by Congress with administering the Medicare statute." *Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012). The part of the program at issue in this case, Part A, covers insurance benefits for inpatient hospital and other institutional care. *See* 42 U.S.C. §§ 1395c to 1395i–4. In general, no payment may be made under Medicare Part A unless the services provided were reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A).

In *Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48 (4th Cir. 2016),[3] the Fourth Circuit outlined the Medicare appeals process:

> To obtain reimbursement for Medicare services, a healthcare provider must, in the first instance, submit a claim to a Medicare Administrative Contractor, a private contractor retained by HHS to make an initial determination regarding whether and in what amount the claim should be paid. *See* 42 U.S.C. §§ 1395ff(a), 1395kk–1(a). That determination by the Medicare Administrative Contractor may, under a program that Congress established in 2010, be audited by a different third-party government contractor, known as a Recovery Audit Contractor. *See id.* § 1395ddd(h)(3). Congress created that audit program to serve "the purpose of . . . recouping overpayments," and it incentivized the Recovery Audit Contractors by paying them "on a contingent basis for collecting overpayments." *Id.* § 1395ddd(h)(1). Healthcare providers wishing to challenge these initial claim determinations by the Medicare Administrative Contractor or the Recovery Audit Contractor must pursue a comprehensive, four-step administrative review process before seeking review in court.

[3] In that case, plaintiff sought a declaratory judgment and writ of mandamus compelling the Secretary to resolve plaintiff's numerous pending administrative appeals. While the Fourth Circuit acknowledged that "the delay in the administrative process for Medicare reimbursement is incontrovertibly grotesque," it affirmed the district court's holding that the issuance of mandamus was not appropriate and that the political branches were better suited to address the delay. 816 F.3d at 50.

At the *first* step, a healthcare provider dissatisfied with either the initial determination or the results of an audit may seek a redetermination from the original Medicare Administrative Contractor. *See* 42 U.S.C. § 1395ff(a)(3). At the *second step*, if the healthcare provider is dissatisfied with the redetermination, it may seek reconsideration by a Qualified Independent Contractor ("QIC") another third-party government contractor retained to independently "review the evidence and findings upon which the [previous determination was] based." 42 C.F.R. § 405.968(a)(1); 42 U.S.C. § 1395ff(c). In doing so, the QIC may receive and consider "any additional evidence the parties submit or that the QIC obtains on its own." 42 C.F.R. § 405.968(a)(1). At the *third step*, the healthcare provider may challenge the QIC's decision by requesting a hearing before an ALJ. *See* 42 U.S.C. § 1395ff(d)(1); 42 C.F.R. § 405.1000. The ALJ hearing process is administered by OMHA [*i.e.*, Office of Medicare Hearings and Appeals], a division within HHS that is independent of and funded through an appropriation separate from the division that oversees the contractors' review during the first two steps of the administrative review process. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108–173, § 931, 117 Stat. 2066, 239699; Statement of Organization, Functions, and Delegations of Authority, 70 Fed.Reg. 36386–04 (June 23, 2005). At the *fourth step*, the healthcare provider may appeal the ALJ's decision to the Departmental Appeals Board for *de novo* review. *See* 42 U.S.C. § 1395ff(d)(2). The Departmental Appeals Board's decision becomes the final decision of the Secretary, which may then be reviewed in court. *See id.* § 1395ff(b)(1)(A); 42 C.F.R. § 405.1130.

The Medicare Act establishes deadlines for each step in the administrative review process and specifies the consequences when such deadlines are not met. The Act directs that the first two steps of administrative review be completed by the [MAC] and the QIC, respectively, within 60 days. 42 U.S.C. §§ 1395ff(a)(3)(C)(ii), 1395ff(c)(3)(C)(i). If the QIC fails to meet this deadline, the healthcare provider may bypass the QIC determination and "escalate" the process by requesting a hearing before an ALJ, even though a decision by the QIC is ordinarily a prerequisite to such a hearing. *Id.* § 1395ff(c)(3)(C)(ii). With respect to the adjudication by an ALJ, the Medicare Act provides that an ALJ "shall conduct and conclude a hearing on a decision of a [QIC] . . . and render a decision on such hearing by not later than the end of the 90–day period beginning on the date a request for hearing has been timely filed." *Id.* § 1395ff(d)(1)(A); *see also* 42 C.F.R. § 405.1016(c) (providing a 180–day deadline if the appeal had been escalated past the QIC level). If the ALJ does not render a decision before the deadline, the healthcare provider may bypass the ALJ and again escalate the process by "request[ing] a review by the Departmental Appeals Board . . ., notwithstanding any requirements for a hearing for purposes of the party's right to such a review." 42 U.S.C. § 1395ff(d)(3)(A). Finally, if the Departmental Appeals Board does not conclude its review within 90 days, *id.* § 1395ff(d)(2)(A), or within 180 days if the appeal had been escalated past the ALJ level, 42 C.F.R. § 405.1100(d), the healthcare provider "may seek judicial review [in a United States district court], notwithstanding any requirements for a hearing for purposes

> of the party's right to such judicial review," 42 U.S.C. § 1395ff(d)(3)(B); *see also* 42 C.F.R. § 405.1132.
>
> In sum, in order to exhaust the administrative process for reimbursement of Medicare services, a healthcare provider must present the claim in the first instance to a Medicare Administrative Contractor and thereafter engage the process of review and appeal set forth in § 1395ff. While the statute imposes deadlines for completion at each step of the process, it also anticipates that the deadlines may not be met and thus gives the healthcare provider the option of bypassing each step and escalating the claim to the next level, ultimately reaching judicial review by a United States district court within a relatively prompt time.

816 F.3d at 53–54.

II. CASE HISTORY AND COURSE OF TREATMENT OF M.H. AND C.B.

CFVHS's complaint arises from its claim against HHS for reimbursement in the principal amount of approximately $66,000.00 for services provided at its inpatient rehabilitation facility ("IRF") to M.H. from 25 June 2013 through 10 July 2013 and to C.B. from 20 April 2012 through 9 May 2012. Administrative Record ("AR") 35, 40. The principal amount of the claim for services to M.H. totals $44,665.95, AR 3731, and the amount for services to C.B. $21,375.36, AR 520, 528.

A. M.H.

M.H. was admitted to the hospital on 21 June 2013 and a consultation for the appropriateness of IRF care was conducted by Zane Walsh, M.D. on 24 June 2013. AR 3607-09. In the consultation, Dr. Walsh identified the following diagnoses for M.H.: (1) left frontal infarct; (2) multiple prior infarcts; (3) coronary artery disease; (4) status post CABG (*i.e.*, coronary artery bypass grafting); (5) osteoarthritis; (6) status post bilaterally knee arthroplasty; (7) spinal stenosis; (8) renal artery stenosis; (9) vertebrobasilar insufficiency; (10) positive cardiolipin antibodies; (11) gouty arthritis; (12) hyperlipidemia; and (13) adult onset diabetes. AR 3607.

Dr. Walsh described the history of M.H.'s then present illness as follows:

> This is a pleasant gentleman known to me from prior rehabilitation. He was recently in rehabilitation, did well and went home. While he was in outpatient therapy he had acute increase in right-sided weakness. He was admitted, had a MRI and was found to have subacute infarct. He has been managed conservatively. He had cardiac enzymes which were unremarkable.
>
> He is having an EEG. I am asked to evaluate for transfer back to rehab.

AR 3607.

Dr. Walsh's review of symptoms stated:

> Patient denies headache or nausea. No chest pain or shortness of breath. No abdominal pain. Says his primary difficulty is his balance and getting to standing. Once he gets standing he says he does better. He is unable to get out [of] a chair by hi[m]self. He wants to be independent, at least with assistive device prior to discharge home.

AR 3608.

Dr. Walsh recommended the following IRF care for M.H.:

> 1. Patient is a good candidate for acute inpatient rehabilitation. I believe he can tolerate 3 hours of therapy a day 5 days a week, specifically 2 hour[s] of physical therapy (PT) a day 5 days a week for gait training, transfer training strengthening, activities of daily living (ADL) retraining. Additional 1 hour of occupational therapy a week for ADL retraining. I believe his risk of complications is moderate in rehab.
> 2. I anticipate his length of stay will be about 2 weeks.
> 3. I anticipate he will improve to where he will be able to go home with the wife. He previously did well in rehab.
> 4. I have informed him that I am likely not going to place him back in warm water therapy at discharge. They understood this.

AR 3609.

M.H. was discharged from the IRF on 10 July 2013, CFVHS's claim for his care was processed by the Medicare Administrative Contractor ("MAC") for CFVHS's region, and the MAC declined to remit payment. AR 40. CFVHS timely filed its appeal requesting a redetermination and on 2 January 2014, the MAC issued a redetermination decision upholding

the denial. AR 3852-68. CFVHS requested reconsideration by the QIC on 20 March 2014, AR 3850, and the QIC issued a reconsideration decision upholding the denial by the RAC on 3 April 2014, AR 3841-46. On 20 May 2014, CFVHS appealed the QIC's decision to an administrative law judge ("ALJ"), but thereafter escalated its appeal to the final level of administrative appeal, the Medicare Appeals Council of the Department Appeals Board ("DAB"[4]), on 31 October 2014. AR 64-69. On 15 May 2015, the DAB issued its final agency decision upholding the denial of plaintiff's claim as to M.H. AR 29-43.

On 17 July 2015, plaintiff commenced this proceeding for judicial review of the DAB's decision as to the claim for M.H., as well as C.B., pursuant to 42 U.S.C. § 405(g). *See* Compl. (D.E. 1).

B. C.B.

Initial preadmission screening was conducted for C.B. by Dr. Walsh on 18 April 2012 following her admission to the hospital the preceding day. AR 97-99. In his notes on the consultation, Dr. Walsh made the following diagnoses: (1) posterior circulation stroke including right medial pons and bilateral occipital lobes; (2) recent multiple falls with gait disturbance; (3) coronary artery disease, status post coronary artery bypass graft; (4) hyperlipidemia; (5) chronic anemia; and (6) prior leg/patella fracture. AR 97. Dr. Walsh described C.B.'s history as follows:

> This is a 91-year-old lady admitted on 04/17/2012 by Dr. Stewart. She had had multiple falls and confusion. She had been worked up as an outpatient. She had MRI which showed the above. She subsequently was admitted. She was seen in consultation by Dr. Paul E. Szwejbka. I am asked to evaluate for rehab needs.

AR 97.

In his recommendations, Dr. Walsh stated:

[4] Though the Secretary uses the acronym "MAC" for the Medicare Appeals Council of the Department Appeals Board, the court will use the acronym "DAB" for it to avoid confusion with the Medicare Administrative Contractor.

> We will see how she does with physical therapy. Her and her family feel that inpatient rehabilitation would be beneficial to her. They had been there before after her patellar fracture and she did well for several years until she has had these recent events.
>
> If she is tolerating and benefiting from acute rehab, then I would be glad to move her for more intensive therapy to Cape Fear Valley Rehabilitation Center.

AR 98. In his 20 April 2012 orders admitting her to IRF, Dr. Walsh indicated that C.B. would receive physical therapy, occupational therapy, and therapeutic recreation. AR 154.

Also on 20 April 2012, the day C.B. was admitted to the IRF, Dr. Walsh completed a post-admission history and physical in which he restated C.B.'s history:

> This 91-year-old lady, premorbidly independent, had multiple falls and confusion. Magnetic resonance imaging (MRI) showed posterior circulation stroke. She was placed on Aggrenox. She was started on physical therapy and occupational therapy. I saw the patient on 04/18/2012 and felt her appropriate for inpatient rehabilitation; she is being admitted for this.

AR 624.

He outlined her plan as follows:

> 1. Inpatient rehabilitation to include physical therapy b.i.d. for gait training and transfer training and occupational therapy for retraining in activities of daily living (ADL).
> 2. She will be seen daily by Physical Medicine and Rehabilitation.
> 3. Aggrenox will be continued
> 4. TED [*i.e.*, thrombo-embolic deterrent] hose will be used. She has excellent strength

AR 625.

Dr. Walsh estimated the length of her stay to be 10 to 14 days. AR 625. He identified the goals for her stay as modified independence to supervision in mobility and activities of daily living, decrease in falls, and completion of family education. AR 625. He estimated her prognosis to reach her goals as good. AR 625. C.B. was discharged on 9 May 2012. AR 35.

The claim for C.B's care was initially processed and paid by the MAC. AR 35-36. Thereafter, CFVHS was notified that C.B.'s claim was subject to a post-payment review by a Recovery Audit Contractor ("RAC"). AR 36. On 27 June 2013, the RAC denied coverage for the claim. AR 36, 519. CFVHS timely filed its appeal requesting a redetermination of the RAC's decision on 15 July 2013. AR 50. On 29 August 2013, the MAC issued a redetermination decision, upholding the denial by the RAC. AR 531-34. CFVHS requested reconsideration by the QIC, and on 17 December 2013, the QIC issued a reconsideration decision upholding the denial by the RAC, AR 537-542. On 12 February 2014, CFVHS appealed the QIC's decision to an ALJ, AR 549-53, but thereafter escalated its appeal to the DAB on 31 October 2014. AR 48-54. On 15 May 2015, in the same final agency decision concerning the claim submitted for services to M.H., the DAB upheld the denial of plaintiff's claim with respect to C.B. AR 29-43.

As noted, on 17 July 2015, plaintiff commenced this proceeding for judicial review of the DAB's decision as to the claim for C.B., as well as M.H., pursuant to 42 U.S.C. § 405(g). *See* Compl.

III. THE DAB'S DECISION

The DAB denied plaintiff's claims on the grounds that

> the IRF services at issue for C.B. and M.H. are not medically reasonable and necessary under section 1862(a) (1) of the Social Security Act (Act) because the documentation requirements for the preadmission screening in 42 C.F.R. section 412.622(a) (4) are not met.

AR 30; 38 (C.B.); 41 (M.H.); 43 (C.B. and M.H.). The DAB reasoned that "IRF care is only considered by Medicare to be reasonable and necessary under 1862(a) (1) (A) of the Act if the patient meets all of the requirements outlined in 42 CFR §§ 412.622(a) (3), (4), and (5), as interpreted in Chapter 1, section 110 of the MBPM [*i.e.*, Medicare Benefit Policy Manual]."

AR 32. The failure of the services provided M.H. and C.B. to satisfy the preadmission documentation requirements in 42 C.F.R. § 412.622(a)(4) as interpreted in MBPM chapter 1, section 110.1.1 precluded these services from meeting all the regulatory requirements to be considered reasonable and necessary, and therefore the services were not reasonable and necessary. *See* AR 41.

In presenting its analysis, the DAB quoted 42 C.F.R. § 412.622(a)(4), including the provision addressing preadmission documentation, subsection (a)(4)(i). AR 33-34. It also recited verbatim the MBPM provision on preadmission documentation:

> The preadmission screening documentation must indicate the patient's prior level of function (prior to the event or condition that led to the patient's need for intensive rehabilitation therapy), expected level of improvement, and the expected length of time necessary to achieve that level of improvement. It must also include an evaluation of the patient's risk for clinical complications, the conditions that caused the need for rehabilitation, the treatments needed (i.e., physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), expected frequency and duration of treatment in the IRF, anticipated discharge destination, any anticipated post-discharge treatments, and other information relevant to the care needs of the patient. *Id.*

AR 34 (quoting without quotation marks MBPM ch. 1 § 110.1.1).

The DAB also presented a separate analysis of the claim for each beneficiary. With respect to M.H., the DAB found that "the information provided on the rehabilitation consultation notes does not provide the information needed to understand the physician's rationale for ordering intensive rehabilitation services at the IRF level of care." AR 41. It explained:

> In this case, the information provided on the rehabilitation consultation notes does not provide the information needed to understand the physician's rationale for ordering intensive rehabilitation services at the IRF level of care. For example, a reviewer cannot determine the beneficiary's prior level of function from general information such as the facts that the beneficiary had a recent IRF stay, did well and returned home, and was participating in outpatient therapy at the time of the stroke leading to the IRF stay related to this claim. *See* Exh. 4, at 32-34. A general statement that the beneficiary is expected to go home with his wife does

> not describe the anticipated functional level on discharge in meaningful clinical detail.

AR 41. The DAB concluded that, as a result of these deficiencies, M.H. failed to meet the preadmission documentation requirements of 42 C.F.R. § 412.622(a)(4) and thereby did not meet all the regulatory requirements, as required, for the IRF services provided him to be considered reasonable and necessary. AR 41-42. The QIC decision had also denied the claim for M.H. for lack of adequate preadmission documentation, although the deficiencies it found were not all the same as those found by the DAB. *Compare* AR 3838 *with* AR 41.

With respect to C.B.'s preadmission documentation, the DAB found it insufficient for three principal reasons. First, it found that

> the [consultation] notes do not contain the specific information required in the preadmission screening, such as which treatments are needed, the expected frequency and duration of rehabilitation treatment in the IRF and the beneficiary's expected level of improvement. *See* MBPM, Ch. 1, § 110.1.1; *see also* 42 C.F.R. § 412.622(a)(4).

AR 37. Second, the DAB found that the preadmission documentation lacked language explicitly recommending IRF services, leaving in doubt whether IRF services were needed over the care plaintiff was already receiving. AR 38. Third, the DAB found that there was no indication in the documentation that a multidisciplinary approach was needed in the case because there was no indication that C.B. required any discipline of therapy aside from physical therapy. AR 38. The DAB therefore concluded, as with M.H., that plaintiff failed to satisfy the preadmission documentation requirements of 42 U.S.C. § 412.622(a)(4) and thereby did not meet all the regulatory requirements, as required, for the IRF services provided C.B. to be considered reasonable and necessary. AR 38-39.

The QIC also denied the claim for C.B. on the basis of deficiencies in preadmission documentation. AR 541. The deficiencies found by the QIC were not all the same as those

found by the DAB. *Compare* AR 541 *with* AR 37-38. Moreover, the QIC found that notwithstanding the defects in the preadmission documentation, the documentation overall showed that the IRF services provided C.B. were reasonable and necessary. AR 541. The DAB expressly rejected this finding as dicta because "IRF care is only considered by Medicare to be reasonable and necessary . . . if all of the requirements outlined in 42 C.F.R. §§ 412.622 (a) (3), (4), and (5) are met." AR 38-39.

The DAB found that in the cases of both C.B. and M.H. plaintiff could reasonably have been expected to know that the services at issue would be denied as not medically reasonable and necessary because the documentation requirements were not met. AR 42. It accordingly concluded that plaintiff was liable for the IRF services furnished to both C.B. and M.H. AR 43.

APPLICABLE LEGAL PRINCIPLES

I. STANDARD OF REVIEW

The standard of review for final decisions of the Secretary on Medicare benefits is set forth in 42 U.S.C. § 405(g). Under 42 U.S.C. § 405(g), judicial review of such conditions is limited to considering whether the Secretary's decision is supported by substantial evidence in the record and whether the appropriate legal standards were applied. *See Richardson v. Perales*, 402 U.S. 389, 390, 401 (1971); *Hays v. Sullivan*, 907 F.2d 1453, 1456 (4th Cir. 1990). Substantial evidence supporting factual findings is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Perales*, 402 U.S. at 401 (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)). It is more than a scintilla of evidence, but somewhat less than a preponderance. *Id*. Unless the court finds that the Secretary's decision is not supported by substantial evidence, the Secretary's decision must be upheld. *Smith v.*

Schweiker, 795 F.2d 343, 345 (4th Cir. 1986); *Blalock v. Richardson*, 483 F.2d 773, 775 (4th Cir. 1972).

The court may not substitute its judgment for that of the Secretary as long as the decision is supported by substantial evidence. *Hunter v. Sullivan*, 993 F.2d 31, 34 (4th Cir. 1992) (per curiam). In making its assessment, the court may not make findings of fact, revisit inconsistent evidence, or make determinations of credibility. *See Craig v. Chater*, 76 F.3d 585, 589 (4th Cir. 1996); *King v. Califano*, 599 F.2d 597, 599 (4th Cir. 1979). A Secretary's decision based on substantial evidence must be affirmed, even if the reviewing court would have reached a different conclusion. *Blalock*, 483 F.2d at 775. A reviewing court is limited, however, to upholding an agency action only on the basis articulated in the decision and may not consider post-hoc rationalizations offered by the agency. *See Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 631 n.31 (1980); *see also Prof'l Massage Training Ctr., Inc. v. Accreditation All. of Career Sch. & Colleges*, 781 F.3d 161, 174–75 (4th Cir. 2015) ("In considering whether the denial was supported by substantial evidence, we confine ourselves to the record that was considered by the accrediting agency at the time of the final decision.").

Before a court can determine whether a decision is supported by substantial evidence, it must ascertain whether the Secretary has considered all relevant evidence and sufficiently explained the weight given to probative evidence. *See Sterling Smokeless Coal Co. v. Akers*, 131 F.3d 438, 439-40 (4th Cir. 1997). "Judicial review of an administrative decision is impossible without an adequate explanation of that decision by the administrator." *DeLoatche v. Heckler*, 715 F.2d 148, 150 (4th Cir. 1983).

Separate from the Secretary's handling of factual matters, his decisions are governed by the Administrative Procedure Act, which requires courts to review whether the agency's decision

was "arbitrary, capricious, an abuse of discretion, . . . otherwise not in accordance with law; . . . [or] without observance of procedure required by law." 5 U.S.C. § 706(2); *Almy*, 679 F.3d at 302. The court's review under this standard is deferential "'with a presumption in favor of finding the agency action valid.'" *Almy*, 679 F.3d at 302 (quoting *Ohio Vall. Envt'l Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009)). An agency action is generally not considered arbitrary and capricious or an abuse of discretion "so long as 'the agency has examined the relevant data and provided an explanation of its decision that includes a rational connection between the facts found and the choice made.'" *Id.* (quoting *Ohio Vall. Envt'l Coal.*, 556 F.3d at 192) (internal quotations omitted); *U.S. Telecom Ass'n v. FCC*, 227 F.3d 450, 460 (D.C. Cir. 2000) (noting that under the arbitrary and capricious standard '"an agency must cogently explain why it has exercised its discretion in a given manner' and that explanation must be 'sufficient to enable [the court] to conclude that the [agency's action] was the product of reasoned decisionmaking'" (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995))); *Meridian Lab. Corp. v. Sebelius*, No. 3:11-CV-00406-FDW, 2012 WL 3112066, at *3 (W.D.N.C. 31 July 2012) ("Further, the 'arbitrary and capricious' standard is a 'highly deferential standard which presumes the validity of the agency's action.'" (quoting *Nat. Res. Def. Council v. EPA*, 16 F.3d 1395, 1400 (4th Cir. 1993)).

Coupled with these statutory directives are several judicial doctrines. For example, the Secretary's assessment of whether a claim is reasonable and necessary is entitled to deference from the court. *See Almy*, 679 F.3d at 302 ("[I]it is well recognized that the Secretary's interpretation of what is 'reasonable and necessary' under the Medicare Act is entitled to judicial deference . . . ."). Similarly, the Secretary's interpretation of regulations implementing the Medicare Act is also entitled to deference. *Id.* (noting that courts must "give an agency's view of

its own regulations 'controlling weight unless it is plainly erroneous or inconsistent with the regulation'" (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945))).

II. REGULATORY REQUIREMENTS FOR IRF SERVICES

As noted in the DAB's decision, there are five requirements a patient must meet for care in an IRF to be deemed reasonable and necessary. Four of these requirements are set forth in 42 C.F.R. § 412.622(a)(3), which reads:

> (3) In order for an IRF claim to be considered reasonable and necessary under section 1862(a)(1) of the [Medicare] Act, there must be a reasonable expectation that the patient meets all of the following requirements at the time of the patient's admission to the IRF—
>
> (i) Requires the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy), one of which must be physical or occupational therapy.
>
> (ii) Generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF. Benefit from this intensive rehabilitation therapy program is demonstrated by measurable improvement that will be of practical value to the patient in improving the patient's functional capacity or adaptation to impairments. The required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.
>
> (iii) Is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation therapy program that is described in paragraph (a)(3)(ii) of this section.
>
> (iv) Requires physician supervision by a rehabilitation physician, defined as a licensed physician with specialized training and experience in inpatient rehabilitation. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the

> patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.

42 C.F.R. § 412.622(a)(3).

The required documentation relating to these requirements is specified in 42 C.F.R. § 412.622(a)(4), which provides:

> Documentation. To document that each patient for whom the IRF seeks payment is reasonably expected to meet all of the requirements in paragraph (a)(3) of this section at the time of admission, the patient's medical record at the IRF must contain the following documentation—
>
> (i) A comprehensive preadmission screening that meets all of the following requirements—
>
> (A) It is conducted by a licensed or certified clinician(s) designated by a rehabilitation physician described in paragraph (a)(3)(iv) of this section within the 48 hours immediately preceding the IRF admission. A preadmission screening that includes all of the required elements, but that is conducted more than 48 hours immediately preceding the IRF admission, will be accepted as long as an update is conducted in person or by telephone to update the patient's medical and functional status within the 48 hours immediately preceding the IRF admission and is documented in the patient's medical record.
>
> (B) It includes a detailed and comprehensive review of each patient's condition and medical history.
>
> (C) It serves as the basis for the initial determination of whether or not the patient meets the requirements for an IRF admission to be considered reasonable and necessary in paragraph (a)(3) of this section.
>
> (D) It is used to inform a rehabilitation physician who reviews and documents his or her concurrence with the findings and results of the preadmission screening.
>
> (E) It is retained in the patient's medical record at the IRF.
>
> (ii) A post-admission physician evaluation that meets all of the following requirements—
>
> (A) It is completed by a rehabilitation physician within 24 hours of the patient's admission to the IRF.
>
> (B) It documents the patient's status on admission to the IRF, includes a comparison with the information noted in the preadmission screening documentation, and serves as the basis for the development of the overall individualized plan of care.
>
> (C) It is retained in the patient's medical record at the IRF.

> (iii) An individualized overall plan of care for the patient that meets all of the following requirements—
>
> (A) It is developed by a rehabilitation physician, as defined in paragraph (a)(3)(iv) of this section, with input from the interdisciplinary team within 4 days of the patient's admission to the IRF.
>
> (B) It is retained in the patient's medical record at the IRF.

42 C.F.R. § 412.622(a)(4).

Finally, the fifth requirement is that the patient needs an interdisciplinary team approach to care. It is set forth in 42 C.F.R. § 412.622(a)(5), which reads:

> (5) Interdisciplinary team approach to care. In order for an IRF claim to be considered reasonable and necessary under section 1862(a)(1) of the [Medicare] Act, the patient must require an interdisciplinary team approach to care, as evidenced by documentation in the patient's medical record of weekly interdisciplinary team meetings that meet all of the following requirements—
>
> (A) The team meetings are led by a rehabilitation physician as defined in paragraph (a)(3)(iv) of this section, and further consist of a registered nurse with specialized training or experience in rehabilitation; a social worker or case manager (or both); and a licensed or certified therapist from each therapy discipline involved in treating the patient. All team members must have current knowledge of the patient's medical and functional status.
>
> (B) The team meetings occur at least once per week throughout the duration of the patient's stay to implement appropriate treatment services; review the patient's progress toward stated rehabilitation goals; identify any problems that could impede progress towards those goals; and, where necessary, reassess previously established goals in light of impediments, revise the treatment plan in light of new goals, and monitor continued progress toward those goals.
>
> (C) The results and findings of the team meetings, and the concurrence by the rehabilitation physician with those results and findings, are retained in the patient's medical record.

42 C.F.R. § 412.622(a)(5). As can be seen, this fifth requirement does not have the same documentation requirements as the initial four requirements. *Id.*

III. CRITERIA FOR PREADMISSION DOCUMENTATION UNDER THE MBPM

The MBPM defines IRF as "intensive rehabilitation therapy in a resource intensive inpatient hospital environment for patients who, due to the complexity of their nursing, medical

management, and rehabilitation needs, require and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to the delivery of rehabilitation care." MBPM ch. 1 § 110, 2006 WL 2513828, at *17.

The MBPM describes the preadmission screening process for IRF services and specifies criteria for documentation of preadmission screening, as follows:

> A preadmission screening is an evaluation of the patient's condition and need for rehabilitation therapy and medical treatment that must be conducted by licensed or certified clinician(s) within the 48 hours immediately preceding the IRF admission. A preadmission screening that includes all of the required elements, but that is conducted more than 48 hours immediately preceding the IRF admission, will be accepted as long as an update is conducted in person or by telephone to document the patient's medical and functional status within the 48 hours immediately preceding the IRF admission in the patient's medical record at the IRF. The preadmission screening in the patient's IRF medical record serves as the primary documentation by the IRF clinical staff of the patient's status prior to admission and of the specific reasons that led the IRF clinical staff to conclude that the IRF admission would be reasonable and necessary. As such, IRFs must make this documentation detailed and comprehensive.
>
> *The preadmission screening documentation must indicate the patient's prior level of function (prior to the event or condition that led to the patient's need for intensive rehabilitation therapy), expected level of improvement, and the expected length of time necessary to achieve that level of improvement. It must also include an evaluation of the patient's risk for clinical complications, the conditions that caused the need for rehabilitation, the treatments needed (i.e., physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), expected frequency and duration of treatment in the IRF, anticipated discharge destination, any anticipated post-discharge treatments, and other information relevant to the care needs of the patient.*
> . . . .
>
> The IRF is responsible for developing a thorough preadmission screening process for patients admitted to the IRF from the home or community-based environment, which is expected to include all of the required elements described in this section. However, such admissions may not necessarily involve the use of medical records from a prior hospital stay in another inpatient hospital setting unless such records are pertinent to the individual patient's situation.
>
> Individual elements of the preadmission screening may be evaluated by any clinician or group of clinicians designated by a rehabilitation physician, as long as the clinicians are licensed or certified and qualified to perform the evaluation

> within their scopes of practice and training. Although clinical personnel are required to evaluate the preadmission screening information, each IRF may determine its own processes for collecting and compiling the preadmission screening information. The focus of the review of the preadmission screening information will be on its completeness, accuracy, and the extent to which it supports the appropriateness of the IRF admission decision, not on how the process is organized.
> . . . .
>
> All preadmission screening documentation (including documents transmitted from the referring hospital or other prior inpatient hospital stay, if applicable) must be retained in the patient's medical record at the IRF.
>
> "Trial" IRF admissions, during which patients were sometimes admitted to IRFs for 3 to 10 days to assess whether the patients would benefit significantly from treatment in the IRF or other settings, are no longer considered reasonable and necessary. Such determination must be made through a careful preadmission screening prior to the patient's admission to the IRF.

MBPM ch. 1 § 110.1.1, 2006 WL 2513828, at *18-19 (emphasis added).

OVERVIEW OF PLAINTIFF'S CONTENTIONS

Plaintiff seeks reversal of the DAB's decision and reimbursement for C.B. and M.H.'s IRF care on the grounds that the DAB erred in relying on the criteria in the MBPM, rather than the requirements in the regulation on such documentation, 42 C.F.R. § 412.622(a)(4), in determining that the preadmission documentation for both patients was insufficient. Alternatively, plaintiff argues that the DAB's determination that the preadmission documentation for both patients did not satisfy the requirements in 42 C.F.R. § 412.622(a)(4) and the criteria in the MBPM is not supported by substantial evidence. Each ground is addressed in turn below.

THE DAB'S RELIANCE ON THE MBPM IN DETERMINING THE PREADMISSION DOCUMENTATION FOR C.B. AND M.H. TO BE INSUFFICIENT

I. APPLICABLE LEGAL PRINCIPLES

The law makes a distinction between substantive rules and interpretive rules. As explained by the First Circuit:

> The APA requires publication of proposed agency rules that are substantive followed by a period for public consideration and comment. 5 U.S.C. § 553(b), (c)2. Interpretive rules are not subject to notice and comment requirements. If a rule creates rights, assigns duties, or imposes obligations, the basic tenor of which is not already outlined in the law itself, then it is substantive. *Ohio Dep't of Human Servs. v. HHS*, 862 F.2d 1228, 1233 (6th Cir. 1988). A substantive rule "has the force of law," while an interpretive rule is "merely a clarification or explanation of an existing statute or rule" and is "'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" *Guardian Fed. Sav. & Loan Ass'n v. FSLIC*, 589 F.2d 658, 664–65 (D.C. Cir. 1978) (quoting *United States Department of Justice, Attorney General's Manual on the Administrative Procedures Act*, at 30 n. 3 (1947)). An interpretive rule creates no law and has no effect beyond the statute. *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 876 (D.C. Cir. 1979).

La Casa Del Convaleciente v. Sullivan, 965 F.2d 1175, 1177–78 (1st Cir. 1992); *Shalala v. Guernsey Mem'l Hosp.*,514 U.S. 87, 100 (1995) (holding that a rule is exempt from the formal notice and comment process if it does not "effect a substantive change in the regulations" (internal citations omitted)). In other words, a substantive rule creates new law, whereas an interpretative rule clarifies or interprets existing law.

It is not permissible for an agency to create substantive changes to regulatory requirements through informal guidance. *Chistensen v. Harris County*, 529 U.S. 576, 588 (2000) ("To defer to the agency's position would be to permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation."); *Lodge v. Burwell*, No. 3:15-CV-390 (JBA), 2016 WL 7493954, at *9 (D. Conn. 30 Dec. 2016) ("Agencies cannot do an end-run around notice-and-comment rulemaking by promulgating ambiguous regulations that simply parrot ambiguous statutory language, setting forth interpretive guidance to those ambiguous regulations, and then demanding deference over those agency interpretations."); *Chan v. U.S. Citizenship & Immigration Servs.*, 141 F. Supp. 3d 461, 469 (W.D.N.C. 2015) ("[A] guidance document or interpretive rule that is treated like a legislative rule is an impermissible circumvention of the notice and comment procedures required by the APA.").

In order to distinguish substantive rules from interpretive ones, the court must assess whether the rule '"effects a substantive regulatory change to the statutory or regulatory regime.'" *Mountain States Health All. v. Burwell*, 128 F. Supp. 3d 195, 205 (D.D.C. 2015) (quoting *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014)). This determination is not always straight forward. *Air Transp. Ass'n of Am. v. FAA*, 291 F.3d 49, 55 (D.C. Cir. 2002) ("The distinction between a substantive rule and an interpretive rule can be less than clear-cut.").

For example, in *Clarian Health W., LLC v. Burwell*, No. 14-CV-0339 (KBJ), 2016 WL 4506969, at *12 (D.D.C. 26 Aug. 2016), the court reviewed a provision in a Medicare Claims Processing Manual that purportedly intrepreted a regulation that permitted reconciliation of certain payments, but did not specify the parameters of such reconciliation. 2016 WL 4506969, at *6. The Medicare Claims Processing Manual set out a mandatory two-step procedure detailing a specific reconcilation process. *Id.* The court determined that the agency guidelines in the manual that established the specific criteria for eligibility for reconciliation constituted a substantive rule, not promulgated through notice-and-comment rulemaking. *Id.* The court therefore found that the Secretary's strict reliance on those provisions was error warranting remand. *Id.*

Similarly, in *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490 (D.C. Cir. 2010), several hospitals challenged a provision in an HHS Provider Reimbursement Manual as being improperly legislative. There, the relevant statutory and regulatory language related to reiumbursement of the "reasonable cost" of services, but left a specific determination of what consituted a reasonable cost to the Secretary. *Id.* at 491. The Provider Reimbursement Manual set out certain arbitrary requirements for reimbursement of some insurance costs and expressly differentiated a series of requirements imposed on particular applicants. *Id.* at 491-92. The court

concluded that "there is no way an interpretation of 'reasonable costs' can produce the sort of detailed—and rigid—investment code set forth" in the Provider Reimbursement Manual. *Id.* at 496. The court set aside the Secretary's decision and remanded the case. *Id.*

II. ANALYSIS

Plaintiff argues that because the criteria contained solely in the MBPM are substantive rather than interpretive, it was error for the DAB to deny plaintiff's claims on the basis of noncompliance with one or more of the criteria. The court agrees.

On their face, the criteria go well beyond 42 C.F.R. § 412.622(a)(4) in setting requirements for preadmission documentation. Specifically, as set out in full above, 42 C.F.R. § 412.622(a)(4) requires documentation of a "comprehensive preadmission screening" that meets the following five requirements: (1) it is conducted by a licensed clinician within 48 hours prior to admission, *id.* § 412.622(a)(4)(i)(A); (2) it includes a detailed and comprehensive review of the patient's condition and medical history, *id.* § 412.622(a)(4)(i)(B); (3) it serves as the basis for the initial determination of whether the patient meets the requirements for an IRF admission to be considered reasonable and necessary, *id.* § 412.622(a)(4)(i)(C); (4) it is used to inform a rehabilitation physician who reviews and documents concurrence with the findings and results of the screening, *id.* § 412.622(a)(4)(i)(D); and (5) it is retained in the patient's medical record, *id.* § 412.622(a)(4)(i)(E).

In contrast, the MBPM requires that the preadmission screening documentation include: (1) the patient's prior level of function; (2) the expected level of improvement; (3) the expected length of time necessary to achieve improvement; (4) an evaluation of the patient's risk for clinical complication; (5) the conditions causing the the need for rehabilition; (6) the treatments needed; (7) the expected frequency and duration of treatment in the IRF; (8) the anticipated

discharge destination; (9) any anticipated post-discharge treatments; and (10) any other information relevant to the patient's care needs. MBPM ch. 1 § 110.1.1.

The list of criteria in the MBPM does not merely clarify or interpret the requirements in the regulation, but creates a new standard by specifying particular items of information not provided for in the regulation. Significantly, these criteria are not simply precatory, that is, a list of factors that should be considered in applying 42 C.F.R. § 412.622(a)(4). Had they been, they would be merely interpretive. *See Harris Cty. Hosp. Dist. v. Shalala*, 863 F. Supp. 404 (S.D. Tex. 1994) (holding that provision in Medicare provider reimbursement manual indicating that hospitals "should" use a particular asset test for purposes of Medicare reimbursement of bad debts was interpretive because it merely suggested, but did not require, use of that test), *aff'd*, 64 F.3d 220 (5th Cir. 1995). Rather, the MBPM states that they are mandatory. It provides that the preadmission screening documentation "must indicate" certain matters and "must also include" the remaining matters specified. MBPM ch. 1 § 110.1.1.

Notwithstanding the self-professed mandatory nature of the criteria in the MBPM, the DAB could have treated them as interpretive. Had the DAB used the criteria simply for guidance, instead of as requirements, there may have been no error. But the DAB did not do so. The DAB quoted this section of the MBPM in the "Authorities" section of its decision, which it stated contained the "legal standards that are applicable" in these cases, without altering the mandatory nature of the criteria presented. AR 31, 34. The DAB acknowledged that neither an ALJ nor the DAB is bound by Medicare program guidance such as the MBPM, but stated that it would "give substantial deference to these policies if they are applicable to a particular case." AR 31, 37 (citing 42 C.F.R. § 405.1062(a)). It went on to say, though, that it could "find no reason why [it] should not follow the applicable manual provisions, and [plaintiff] has not

provided any reason for not doing so." AR 37. The DAB errs, of course in effectively making it plaintiff's burden to demonstrate why the DAB should use the criteria in the MBPM in accordance with law. In any event, the DAB's determination shows that it ultimately treated the preadmission documentation provision in the MBPM as a mandatory, substantive rule.

Consistent with this determination by the DAB, the DAB grounded its determination that the rehabilitation consultation notes for M.H. were insufficient because they did not adequately show plaintiff's "prior level of function" or "anticipated functional level on discharge." AR 41. The DAB stated:

> In this case, the information provided on the rehabilitation consultation notes does not provide the information needed to understand the physician's rationale for ordering intensive rehabilitation services at the IRF level of care. For example, a reviewer cannot determine the beneficiary's *prior level of function* from general information such as the facts that the beneficiary had a recent IRF stay, did well and returned home, and was participating in outpatient therapy at the time of the stroke leading to the IRF stay related to this claim. *See* Exh. 4, at 32-34. A general statement that the beneficiary is expected to go home with his wife does not describe the *anticipated functional level on discharge* in meaningful clinical detail.

AR 41 (emphasis added). The "prior level of function" and "expected level of improvement" are, of course, items of information the criteria in the MBPM provide "must" be contained in the preadmission documentation. MBPM ch. 1 § 110.1.1.

The DAB's strict application of the criteria in the MBPM in rejecting the preadmission documentation for M.H. was not in accordance with law and was therefore erroneous. Because the foregoing grounds comprise the sole grounds upon which the DAB denied plaintiff's claim for the IRF care provided M.H., the error cannot be dismissed as harmless. *See, e.g.*, *Garner v. Astrue*, 436 F. App'x 224, 226 n.* (4th Cir. 2011) (applying *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009)); *E. Maine Med. Ctr. v. Burwell*, 159 F. Supp. 3d 109, 116 (D. Me. 2016) ("'The doctrine of harmless error is as much a part of judicial review of administrative action as of

appellate review of trial court judgments.'" (quoting *Save Our Heritage, Inc., v. F.A.A.*, 269 F.3d 49, 61 (1st Cir. 2001))). The error therefore provides an independent basis for denial of the Secretary's motion with respect to plaintiff's claim for IRF services provided to M.H.

As to C.B., the DAB found with respect to C.B. that the 17 April 2012 rehabilitation consultation notes

> do not contain the specific information *required* in the preadmission screening, such as which treatments are needed, the expected frequency and duration of rehabilitation treatment in the IRF and the beneficiary's expected level of improvement. *See* MBPM, Ch. 1, § 110.1.1; *see also* 42 C.F.R. § 412.622(a)(4).

AR 37 (emphasis added). The items of information found to be missing are among those specified by the criteria in the MBPM. The DAB's reliance on the MBPM for its finding is further illustrated by its citation to the MBPM as the primary authority for its finding.

As with the claim for the IRF services rendered to M.H., the DAB's strict application of the criteria in the MBPM as to C.B. was not in accordance with law and was erroneous. Noncompliance with the criteria was, of course, one of three grounds upon which the DAB denied the claim for services to C.B. If the other grounds were proper, the DAB's error in reliance on the criteria in the MBPM would arguably be harmless. As discussed further below, however, the other two grounds are also legally deficient. This error therefore warrants denial of the Secretary's motion as to plaintiff's claim for the IRF services provided C.B.

THE DAB'S DETERMINATION THAT THE PREADMISSION DOCUMENTATION FOR M.H. AND C.B. WAS INSUFFICIENT

Alternatively, plaintiff argues that the DAB's conclusion that the preadmission documentation for M.H. and C.B. did not satisfy the requirements in 42 C.F.R. § 412.622(a)(4) and the criteria in the MBPM is not supported by substantial evidence. The court will address each beneficiary separately.

I. THE PREADMISSION DOCUMENTATION FOR M.H.

As set out previously, the preadmission documentation for M.H. included the following information from Dr. Walsh:

> He was recently in rehabilitation, did well and went home. While he was in outpatient therapy he had acute increase in right-sided weakness. He was admitted, had a MRI and was found to have subacute infarct. He has been managed conservatively.
> . . . .
> Says his primary difficulty is his balance and getting to standing. Once he gets standing he says he does better. He is unable to get out [of] a chair by hi[m]self. He wants to be independent, at least with assistive device prior to discharge home.
> . . . .
> 1. Patient is a good candidate for acute inpatient rehabilitation. I believe he can tolerate 3 hours of therapy a day 5 days a week, specifically 2 hour[s] of physical therapy (PT) a day 5 days a week for gait training, transfer training strengthening, activities of daily living (ADL) retraining. Additional 1 hour of occupational therapy a week for ADL retraining. I believe his risk of complications is moderate in rehab.
> 2. I anticipate his length of stay will be about 2 weeks.
> 3. I anticipate he will improve to where he will be able to go home with the wife. He previously did well in rehab.
> 4. I have informed him that I am likely not going to place him back in warm water therapy at discharge. They understood this.

AR 3607-09.

Again, the DAB found the information in the preadmission documentation insufficient on the following grounds:

> In this case, the information provided on the rehabilitation consultation notes does not provide the information needed to understand the physician's rationale for ordering intensive rehabilitation services at the IRF level of care. For example, a reviewer cannot determine the beneficiary's prior level of function from general information such as the facts that the beneficiary had a recent IRF stay, did well and returned home, and was participating in outpatient therapy at the time of the stroke leading to the IRF stay related to this claim. *See* Exh. 4, at 32-34. A general statement that the beneficiary is expected to go home with his wife does not describe the anticipated functional level on discharge in meaningful clinical detail.

AR 41. Thus, the DAB determined that the preadmission documentation does not adequately show Dr. Walsh's rationale for ordering IRF care because the information provided regarding M.H.'s "prior level of function" and "anticipated functional level on discharge" are too general.

The court finds that these findings are not supported by substantial evidence. As to plaintiff's prior level of function, the DAB characterizes the preadmission documentation as showing merely that M.H. "had a recent IRF stay, did well and returned home, and was participating in outpatient therapy at the time of the stroke leading to the IRF stay" at issue. AR 41. The DAB fails to mention that the preadmission documentation also included the material details that M.H. had an "acute increase in right-sided weakness," "his primary difficulty is his balance and getting to standing," and he "is unable to get out [of] a chair by hi[m]self." AR 3608. Absent any explanation by the DAB as to why these details are insufficient to show plaintiff's prior level of function, the court cannot say that its determination is supported by substantial evidence.

Regarding plaintiff's anticipated functional level on discharge, the DAB characterizes his preadmission documentation as showing simply that he "is expected to go home with his wife." AR 41. But Dr. Walsh noted that plaintiff's "primary difficulty is his balance and getting to standing," "[o]nce he gets standing he says he does better," he "is unable to get out [of] a chair by hi[m]self," and "wants to be independent, at least with assistive device prior to discharge home." AR 3608. An inference that can obviously be drawn from this information is that the anticipated functional level on discharge is restoration of M.H.'s ability to stand and walk, at least with an assistive device. Because of the failure of the DAB to address these specific details in the preadmission documentation and their potential implication for plaintiff's anticipated

functional level on discharge, the court concludes that the DAB's finding regarding plaintiff's anticipated level of functioning on discharge is not supported by substantial evidence.

Taken together, the foregoing detailed information in M.H.'s preadmission documentation regarding his prior level of function and anticipated functional level upon discharge could manifestly be interpreted as showing that Dr. Walsh referred him to IRF care on the rationale that he needed such care to restore his ability to stand up and walk, at least with an assistive device. Again, the failure of the DAB to address this obvious potential implication precludes the court from finding that the DAB's determination on the rationale for the IRF referral is supported by substantial evidence.

The DAB concluded on the basis of the purported failure of the preadmission documentation to reveal Dr. Walsh's rationale for his IRF referral that the documentation fails to satisfy the requirements of 42 C.F.R. § 412.622(a)(4). Because the DAB's determination regarding Dr. Walsh's rationale is not supported by substantial evidence, its determination regarding noncompliance with the regulation is also unsupported by substantial evidence. This and the other errors discussed are obviously not harmless. They accordingly provide an independent basis for denial of the Secretary's motion.

II. THE PREADMISSION DOCUMENTATION FOR C.B.

As noted, C.B.'s initial preadmission consultation was conducted the day after she was admitted to the hospital following a stroke. *See* AR 97. In it, Dr. Walsh identified her diagnoses and history of her condition, specifying diagnoses for (1) posterior circulation stroke including right medial pons and bilateral occipital lobes; (2) recent multiple falls with gait disturbance; (3) coronary artery disease, status post coronary artery bypass graft; (4) hyperlipidemia; (5) chronic anemia; and (6) prior leg/patella fracture. AR 97-99. His recommendation for C.B. was to wait

and see how she handled physical therapy in the hospital setting and that if she tolerated it and benefitted from it he "would be glad to move her for more intensive therapy to Cape Fear Valley Rehabilitation Center." AR 98. Two days later, he signed admission orders directing that she receive physical therapy, occupational therapy, and therapeutic recreation. AR 154.

As also discussed, the DAB concluded that the preadmission documentation for C.B. was insufficient for three principal reasons: (1) it lacked information purportedly required under the MBPM on which treatments were needed, the expected frequency and duration of rehabilitation treatment in the IRF, and the expected level of improvement; (2) it lacked an explicit recommendation for IRF services; and (3) it lacked an indication that C.B. required any discipline of therapy aside from physical therapy. AR 37-38.

Plaintiff argues that the 18 April 2012 preadmission consultation notes and 20 April 2012 admission orders, taken together, suffice to satisfy the documentation requirements for C.B.'s admission to IRF care pursuant to either the regulation or the MBPM and that the DAB erred in to so finding. The court agrees that the DAB's determination regarding the sufficiency of the preadmission documentation for C.B. was erroneous though not on precisely the same terms advanced by plaintiff.

Turning first to the DAB's finding that Dr. Walsh did not recommend IRF care, the consultation notes and admission orders read together do support a finding that Dr. Walsh did recommend IRF services. As noted, Dr. Walsh specifically stated in his 18 April 2012 consultation notes that "[i]f she is tolerating and benefiting from acute rehab, then I would be glad to move her for more intensive therapy to Cape Fear Valley Rehabilitation Center." AR 98. This statement can reasonably be read to signify that he recommended IRF care for C.B. subject to the condition that she tolerated and benefitted from therapy while still in the hospital. His

admission orders two days later can reasonably be read as confirming that the condition was met.

The DAB did not read the consultation notes together with the admission orders, but instead read the consultation notes in a vacuum. It did so despite the fact that Dr. Walsh's imposition of the condition on the referral to IRF care, that C.B. tolerated and benefited from the therapy she received in the hospital, suggested that Dr. Walsh was conducting exactly the type of careful assessment of a beneficiary's suitability for IRF care before making a referral to such care that the regulations are intended to ensure. To essentially punish such a cautious approach appears to run counter to the apparent purpose behind the documentation requirements. The DAB offers no explanation why it did not consider the consultation notes and the admission order together. In the absence of an explanation by the DAB justifying its failure to do so and explaining why the consultation notes and the admission orders read together do not show that Dr. Walsh recommended IRF care, the court cannot say that the DAB's finding regarding the absence of a recommendation for IRF care for C.B. is supported by substantial evidence.[5]

As to the DAB's finding that the preadmission documentation did not meet the criteria under the MBPM, the admission orders do, in fact, indicate the types of therapies that were needed by directing that C.B. be provided physical therapy, occupational therapy, and

[5] As noted, in finding that the consultation notes did not adequately recommend IRF services, the DAB relied in part on a physical therapy record which states that C.B. would complete "further therapy services prior to [discharge]." AR 38 (citing AR 448). The DAB characterizes this statement as evidence that the IRF benefit was impermissibly being used as an alternative to C.B. receiving the full course of treatment in the referring hospital. AR 38. One problem with this analysis is that the record in question postdates C.B.'s admission to the IRF. It documents an evaluation done on 22 April 2012, two days after C.B. was admitted to the IRF. *See* AR 448. The issue presented is, of course, the sufficiency of the preadmission documentation. If recourse may properly be made to post-admission documentation in addressing this issue, the DAB should have considered evenhandedly all the relevant post-admission evidence, much of which tends strongly to show that the IRF services were reasonable and necessary in nature, rather than cherry-pick a single cryptic reference from one record in an effort to support its position. Moreover, the fact that a patient would receive "further therapy services prior to [discharge]" does not necessarily have the sinister meaning the DAB attributes to it. Indeed, the statement could seemingly be made of any patient who was receiving some therapy in the hospital setting prior to referral to an IRF, in which additional therapy services will be provided before the patient's discharge. The DAB has not adequately justified the interpretation it attributes to this statement. In short, this record does not constitute substantial evidence supporting the DAB's finding that the preadmission documentation failed adequately to recommend IRF services for C.B.

therapeutic recreation. AR 154. The DAB again did not consider the admission orders in making its finding or justify its failure to do so. The DAB's finding that the preadmission documentation did not show the treatment that was needed is therefore not supported by substantial evidence.

Contrary to plaintiff's contention, however, neither the 18 April 2012 consultation notes nor the 20 April 2012 admission orders indicate the expected frequency and duration of rehabilitation treatment in the IRF, and the expected level of improvement. This deficiency, though, is not material because, as discussed, the MBPM criteria are not mandatory.

The third reason found by the DAB for the insufficiency of the preadmission documentation for the services provided C.B. was, of course, its purported failure to indicate that C.B. required any discipline of therapy aside from physical therapy. As discussed, however, the admission orders do indicate two types of therapy C.B. was to receive in addition to physical therapy. As to this finding, as with the others, the DAB did not address the admission orders and did not justify its failure to do so. Thus, this finding by the DAB also lacks the support of substantial evidence.

The foregoing deficiencies in the DAB's determination that the preadmission documentation relating to the IRF services provided C.B. are not harmless, but materially affect the grounds upon which the DAB found the preadmission documentation as to C.B. insufficient. They therefore provide another basis for denial of the Secretary's motion.

REVERSAL OF THE DAB'S DECISION AND REMAND FOR REIMBURSEMENT

"Section 405(g) of the Social Security Act authorizes the Court to affirm, modify, or reverse the MAC's decision on Medicare coverage based on the record and the pleadings, with or without remanding for a rehearing. Remanding a case is unnecessary when 'all factual issues

have been resolved and the record can yield but one supportable conclusion.'" *Heart 4 Heart*, 2014 WL 3028684, at *6 (C.D. Ill. 3 July 2014) (quoting *Briscoe ex rel. Taylor v. Barnhart*, 425 F.3d 345, 355 (7th Cir. 2005)); *Lodge v. Burwell*, No. 3:15-CV-390 (JBA), 2016 WL 7493954, at *8 (D. Conn. 30 Dec. 2016) ("Pursuant to 42 U.S.C. § 1395ff(b)(l)(A), which incorporates the substantive standards of 42 U.S.C. § 405(g), this Court is empowered to affirm, modify, or reverse the Secretary's final decision with or without remand.").

Here, as discussed, the DAB's conclusion that the preadmission documentation for M.H. and C.B. is insufficient is based on improper legal standards and not supported by substantial evidence. Moreover, the evidence of record strongly shows that the preadmission documentation is sufficient. Further, there has already been substantial delay in resolution of plaintiff's claims and it is indisputable that there would be substantial additional delay were the court to remand the matter for further proceedings in the Medicare appeals process. Under these circumstances, this matter should be remanded for payment of plaintiff's claims for reimbursement. *See Breeden v. Weinberger*, 493 F.2d 1002, 1012 (4th Cir. 1974) (holding it "appropriate to reverse without remanding where the record does not contain substantial evidence to support a decision denying coverage under the correct legal standard and when reopening the record for more evidence would serve no purpose" and noting the length of time the matter had already been pending in the agency). *Cf. Radford v. Colvin*, 734 F.3d 288, 296 (4th Cir. 2013) (finding remand for further proceedings more appropriate than reversal and payment "[g]iven the depth *and ambivalence* of the medical record" (emphasis added)).

CONCLUSION

For the foregoing reasons, IT IS RECOMMENDED that plaintiff's motion (D.E. 67) for judgment on the pleadings be ALLOWED, the Secretary's motion (D.E. 69) for judgment on the

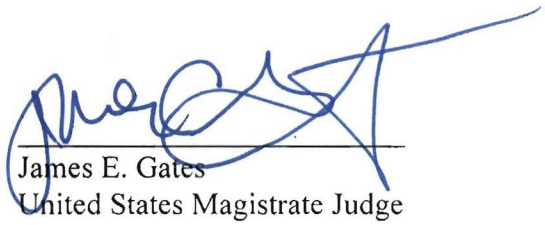
pleadings be DENIED, the Secretary's final decision REVERSED, and this case be REMANDED for payment by the Secretary of the reimbursement claims of plaintiff for the IRF services rendered to beneficiaries M.H. and C.B., plus interest at the current rate published at http://www.hhs.gov/asfr/of/finpollibrary/chronorates.html.

IT IS DIRECTED that a copy of this Memorandum and Recommendation be served on each of the parties or, if represented, their counsel. Each party shall have until 7 March 2017 to file written objections to the Memorandum and Recommendation. The presiding district judge must conduct his own review (that is, make a de novo determination) of those portions of the Memorandum and Recommendation to which objection is properly made and may accept, reject, or modify the determinations in the Memorandum and Recommendation; receive further evidence; or return the matter to the magistrate judge with instructions. *See, e.g.*, 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3); Local Civ. R. 1.1 (permitting modification of deadlines specified in local rules), 72.4(b), E.D.N.C.

If a party does not file written objections to the Memorandum and Recommendation by the foregoing deadline, the party will be giving up the right to review of the Memorandum and Recommendation by the presiding district judge as described above, and the presiding district judge may enter an order or judgment based on the Memorandum and Recommendation without such review. In addition, the party's failure to file written objections by the foregoing deadline will bar the party from appealing to the Court of Appeals from an order or judgment of the presiding district judge based on the Memorandum and Recommendation. *See Wright v. Collins*, 766 F.2d 841, 846-47 (4th Cir. 1985).

Any response to objections shall be filed within three days after the filing of the objections, but in no event later than 10 March 2017.

This 28th day of February 2017.



James E. Gates
United States Magistrate Judge